UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

CAROLYN REECE,

Plaintiff,

v. Case No. C-1-05-322

ASTRAZENECA PHARMACEUTICALS, LP;
ASTRAZENECA LP.

Defendants.

ORDER

Plaintiff Carolyn Reece brings this diversity action against defendants Astrazeneca Pharmaceuticals, LP and Astrazeneca LP (collectively, "Astrazeneca"). The matter is before the Court upon defendants' motion for summary judgment (doc. 39), plaintiff's response in opposition to defendants' motion for summary judgment (doc. 48), and defendants' reply (doc. 52) and upon defendants' proposed findings of fact and conclusions of law (doc. 41). The matter is also before the Court upon defendants' motion to exclude the expert testimony of Dr. Suzanne Parisian (doc. 42), which plaintiff opposes (doc. 49).[1] A hearing on the motions was held on April 26, 2007.

[1]Plaintiff has agreed to withdraw the expert opinions of Dr. Bradley P. Katz and Dr. Radha Krishna Krothapalli, and defendants have withdrawn their motions to exclude their expert opinions (docs. 34, 37). See doc. 64.

I. Introduction

Plaintiff, a resident of Ohio, originally filed this action in the Court of Common Pleas for Butler County, Ohio. Defendants removed the action to this court based on the court's diversity jurisdiction. Plaintiff subsequently filed an amended complaint. Plaintiff makes the following allegations in the amended complaint: Plaintiff was prescribed and used the drug Crestor (rosuvastatin) from April 2004 until approximately July 12, 2004, for the treatment and control of high cholesterol. Defendants, both foreign corporations incorporated in the State of Delaware with their principal place of business in Delaware, were at all relevant times in the business of designing, developing, testing, manufacturing, packaging, labeling, promoting, marketing, advertising, selling, and/or distributing the pharmaceutical Crestor in interstate commerce and in the State of Ohio. At all material times, defendants negligently and/or intentionally designed, developed, tested and manufactured Crestor, an unreasonably dangerous and defective product; they packaged, labeled, promoted, marketed, advertised, sold, and/or distributed Crestor, utilizing information known to fraudulently represent the safety and efficacy of Crestor, and using information known to misrepresent the known dangers and adverse reactions associated with the use of Crestor; and they continued to develop, manufacture, package, label, promote, advertise, market, sell and/or distribute Crestor so as to maximize sales and profits at the expense of public health and safety, including plaintiff's, despite actually knowing that Crestor was causally related to and associated with severe and life threatening complications and side effects, including, but not limited to, rhabdomyolysis[2] and renal failure. As a direct and proximate result of defendants'

[2]"Rhabdomyolysis" is the degeneration of skeletal muscle tissue accompanied by the release of muscle cell contents into the bloodstream. ***Merriam-Webster's Medical Dictionary*** (2002).

acts and omissions, plaintiff has suffered injuries and damages, including physical pain and suffering, mental and emotional anguish and distress, and economic loss, including medical and prescription drug expenses. There is a reasonable probability plaintiff will suffer these injuries and damages in the future. Plaintiff is entitled to an award of punitive damages in that defendants acted with conscious disregard of the foreseeable harm caused by Crestor and with fraud, ill will, recklessness, and/or gross negligence. Defendants acted with willful and intentional disregard of plaintiff's rights.

Based on these allegations, plaintiff brings a claim for strict liability for the defective design and manufacture of Crestor (Count One). Plaintiff alleges that Crestor was marketed to physicians and the general public; she ingested Crestor for the treatment and control of high cholesterol, which was the foreseeable and intended use; Crestor failed to perform as safely as an ordinary consumer would expect in that its use was associated with a high risk of severe physical injury or death resulting from rhabdomyolysis or renal failure; the design was defective in that the benefits associated with the use of Crestor were relatively minor and could have been obtained by the use of alternative treatments and products that could equally or more effectively obtain similar results; the defect in design existed when the product left defendants' possession; at the time Crestor left defendants' possession, defendants knew or should have known of the risks associated with ingesting Crestor; defendants failed to provide plaintiff the warnings or instructions a manufacturer exercising reasonable care would have provided concerning the risk which ultimately caused plaintiff's injury; defendants failed to provide post-marketing warnings or instructions to plaintiff or plaintiff's physician sufficient to convey the true risks associated with the use of Crestor; and plaintiff was injured as a result of defendants' wrongful conduct.

Plaintiff also brings a claim for negligence (Count Two). Plaintiff alleges defendants breached a duty to exercise ordinary care in designing, developing, manufacturing, packaging, labeling, marketing, advertising, selling, and/or distributing Crestor; defendants knew or should have known Crestor created an unreasonable risk of bodily harm; defendants nonetheless continued to market Crestor to physicians and consumers when there were safer alternative methods of treatment; defendants knew or should have known that consumers such as plaintiff would suffer injury or death as a result of defendants' failure to exercise ordinary care; and plaintiff was injured as a direct and proximate result of defendants' negligence.

Plaintiff originally brought claims for breach of express warranty (Count Three), breach of implied warranty (Count Four), fraud (Count Five), and fraudulent concealment (Count Six). Plaintiff has represented that she is withdrawing these claims as well as her strict liability claim based on a defective design theory. Plaintiff is therefore proceeding only on her claims for strict liability based on a failure to warn and for negligence.

II. Undisputed facts

Defendants have submitted proposed findings of fact and conclusions of law in support of their motion for summary judgment pursuant to the Court's Order of August 22, 2005 (doc. 14). Plaintiff has not marked the defendants' proposed findings of fact and conclusions of law true, false or irrelevant as required by the Court's Order. The Court has therefore gleaned the following undisputed facts from the written record and the testimony and arguments presented at the oral hearing.

1. AstraZeneca manufactures and markets Crestor, a prescription medication in the statin class that is used in the treatment of high cholesterol and hyperlipidemia.
2. Pursuant to statute and regulations, AstraZeneca provides physicians with prescribing information and warnings for all of its prescription medications, including Crestor, which is approved by the United States Food and Drug Administration (FDA). The FDA has never required that a warning regarding Crestor be provided directly to consumers.
3. Dr. Barry Webb prescribed Crestor for the treatment of plaintiff's uncontrolled high cholesterol and hyperlipidemia in approximately March or April of 2004. Dr. Webb and his medical practice had a longstanding doctor/patient relationship with plaintiff prior to that time.
4. Plaintiff had been prescribed other medications for approximately 13 years in an unsuccessful attempt to treat her uncontrolled high cholesterol and hyperlipidemia.
5. Prior to her use of Crestor in 2004, plaintiff had been diagnosed with fibromyalgia, a chronic disorder characterized by widespread pain, tenderness, and muscle stiffness.

6. The FDA-approved label and prescribing information for Crestor at the time it was prescribed to plaintiff contained the following bold-faced warning: "**Rare cases of rhabdomyolysis with acute renal failure secondary to myoglobinura have been reported with rosuvastatin [Crestor] and with other drugs in this class."**

7. The label further warns that, "Patients should be advised to promptly report unexplained muscle pain, tenderness, or weakness, particularly if accompanied by malaise or fever. Rosuvastatin therapy should be discontinued if markedly elevated CK levels or myopathy is diagnosed or suspected."

8. At the time he prescribed Crestor to plaintiff, Dr. Webb was aware of the specific risk of rhabdomyolysis with acute renal failure associated with the ingestion of the statin class of drugs in general and Crestor specifically.

9. Dr. Webb was adequately warned of this risk by the FDA-approved label and prescribing information provided by AstraZeneca for Crestor.

10. Dr. Webb took the risk of rhabdomyolysis with acute renal failure into account, along with his knowledge of plaintiff's medical history and his experience in treating plaintiff, when he performed the risk/benefit analysis that led him to prescribe Crestor for plaintiff.

11. At the time he prescribed Crestor for plaintiff, Dr. Webb was aware that acute liver failure secondary to rhabdomyolysis could lead to chronic kidney injury and the need for permanent dialysis.

12. Plaintiff presented at Mercy Fairfield Hospital in July 2004 with complaints of a fall earlier in the day, back pain, and confusion. She was diagnosed with rhabdomyolysis and acute kidney failure. She is now on permanent dialysis as a result.

13. Crestor was the cause of plaintiff's rhabdomyolysis and acute kidney failure.

III. Motion to exclude expert testimony of Suzanne Parisian

A. Standard of review

Federal trial courts have a "gatekeeping" role with regard to the admissibility of proffered expert testimony. ***Daubert v. Merrell Dow Pharmaceuticals, Inc.***, 509 U.S. 579 (1993). The standard for the admission of expert scientific testimony is set forth in Fed. R. Ev. 702. Rule 702 allows such testimony to be admitted if it "will assist the trier of fact to understand the evidence or to determine a fact in issue" and if the witness is qualified as an expert. Rule 702 provides,

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

"[T]he trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." ***Daubert***, 509 U.S. at 589. A court must determine first, whether the expert is proposing to testify to scientific knowledge. ***Id***. at 590. Second, the court must determine whether the evidence will assist the trier of fact to understand the evidence or determine a fact in issue. ***Daubert,*** 509 U.S. at 592. "This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." ***Id***. The Supreme Court in ***Daubert*** recognized that many factors could bear on the inquiry and set out a non-exhaustive list to aid the trial court in its determination. These include whether the theory or

technique can be (and has been) tested; whether the theory or technique has been subjected to peer review and publication; the known or potential rate of error and the existence and maintenance of standards controlling the technique's operation; and the extent to which the theory or technique has been accepted in its field. ***Id***. at 593-94. An additional factor is "'whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying' because the former provides important, objective proof that the research comports with the dictates of good science." ***Smelser v. Norfolk Southern Railway Co.***, 105 F.3d 299, 303 (6th Cir. 1997) (citing ***Daubert*** (on remand), 43 F.3d 1311, 1317 (9th Cir. 1995).

The inquiry under Rule 702 must be a flexible one, and the focus for admissibility must be based "solely on principles and methodology, not on the conclusions they generate." ***Daubert,*** 509 U.S. at 595. "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." ***Id.*** at 596. If the court concludes that the evidence is insufficient to allow a reasonable juror to conclude that the position more likely than not is true, the court is free to prohibit the case from going to the jury. ***Id.***

The party proffering expert testimony has the burden of demonstrating by a "preponderance of proof that the expert whose testimony is being offered is qualified and will testify to . . . knowledge that will assist the trier of fact in understanding and disposing of issues relevant to the case." ***Pride v. BIC Corp.***, 218 F.3d 566, 578 (6th Cir. 2000).

B. The parties' positions

Plaintiff seeks to offer the expert opinions of Dr. Susanne Parisian. Dr. Parisian is a medical doctor who is board-certified in Anatomic and Clinical Pathology. She worked as a medical officer with the FDA's Center for Devices and Radiological Health from 1991-1995. Dr. Parisian has been in general practice, and she worked in emergency medicine for approximately one year. Plaintiff asserts that Dr. Parisian will offer opinions on the following matters on which she has expertise:

1. The regulations governing the approval, labeling, advertising and marketing of pharmaceutical and medical products;
2. The processes by which the FDA determines the efficacy and safety of new drugs and new drug applications;
3. The issues the FDA considers in the development of product labeling and marketing information; and
4. A manufacturer's responsibility within this system.

Plaintiff argues that a layman is not in a position to understand FDA regulations, procedures and requirements. Plaintiff contends that Dr. Parisian will testify as to these matters and assist the trier of fact in determining what duties and responsibilities defendants had with respect to their product and plaintiff and how they acted in that regard. Plaintiff argues that defendants have raised the defense that Crestor was FDA-approved, and she is entitled to present expert testimony as to what that means. She alleges that Dr. Parisian can explain the standards of conduct of a manufacturer within the regulatory framework and how and why defendants did not act reasonably with respect to the use of Crestor and the conducting of safety testing.

Defendants claim that Dr. Parisian lacks the necessary experience and expertise and her opinions are unreliable and irrelevant to this case. Defendants argue that Dr. Parisian's

experience regarding FDA regulatory issues is confined solely to the area of medical devices, not drugs, and the FDA regulatory system relating to drugs is separate and distinct from that pertaining to devices. Defendants allege that Dr. Parisian has demonstrated that she is unfamiliar with the differences in the FDA regulations governing medical devices and pharmaceutical drugs. Defendants argue that Dr. Parisian is not qualified to offer expert testimony on the labeling of drugs, so her opinion that the Crestor label is inadequate must be excluded. Defendants further claim that Dr. Parisian is offering opinions that go beyond FDA regulations and procedures and instead address matters such as the effect of Crestor on kidney function, the safety of Crestor compared to that of other statins, and the ability of patients suffering from fibromyalgia to differentiate pain caused by that condition from pain that may result from muscle injury caused by the use of Crestor and other statins.

Defendants also allege that Dr. Parisian has not treated patients for 16 years and has not received training in nephrology, rheumatology, and cardiology, so that she lacks the necessary education, training and experience to opine on medical issues related to these areas. Defendants argue that her testimony related to renal monitoring, the utility of periodic Creatinine Kinase ("CK") testing for early detection of rhabdomyolysis in patients taking Crestor, whether plaintiff's kidney failure was the result of a unique effect of Crestor unrelated to rhabdomyolysis, and the need for a special warning directed to people suffering from chronic pain are beyond her expertise and should be excluded.

Defendants further argue that Dr. Parisian's methodology is unreliable. They allege that she did not review the protocols for the clinical trials or the Crestor New Drug Application, but she instead relies on the depositions, plaintiff's medical records, the expert report of Dr.

Krothapalli, the package insert for Crestor, one of several medical reviews for Crestor, a Public Citizen Petition to the FDA requesting that Crestor be removed from the market, the FDA's denial of the petition, and selected summaries by FDA employees. Defendants also contend that Dr. Parisian's opinion that the labeling is inadequate for chronic pain patients is without factual foundation. They claim that the only specific information she provides in support of her opinion is plaintiff's injury.

Defendants challenge as unreliable and as having no basis in fact Dr. Parisian's opinion that they should have informed physicians that due to the risks to kidney function, the physician should obtain a baseline serum CK before prescribing Crestor in order to monitor renal function, particularly in the special population of patients with chronic muscle pain syndrome, so as to diagnose without delay adverse effects produced by Crestor, including the risk for rhabdomyolysis, chronic renal failure and death. Defendants assert that Dr. Parisian conceded that the labeling for Crestor was adequate when it was approved and she identified no later information that would have made the labeling inadequate; she concedes the FDA considered the precise issue of renal monitoring and decided not to implement it; and she makes no connection between the proposed monitoring and the plaintiff in this case. They also assert that Dr. Parisian admits she does not know when defendants became aware that the Crestor label was not going to be adequate to protect patients with chronic pain. Finally, defendants allege that Dr. Parisian's opinion that Crestor poses unique risks to kidney function not seen with other statins is irrelevant and should be excluded.

In response, plaintiff contends that defendants' arguments go mainly to the weight to be given Dr. Parisian's testimony. She asserts that Dr. Parisian is qualified by her training in

addition to her knowledge and skill. Plaintiff contends that Dr. Parisian is being called as a regulatory expert to testify regarding the FDA regulatory process, the nature of the FDA's review of product testing, FDA procedures and regulations governing labeling content, adequacy of warnings, post-marketing surveillance, and regulatory standards of conduct and compliance for drug safety. Plaintiff alleges that Dr. Parisian also has experience and knowledge as to a manufacturer's responsibility with regard to safety issues related to the product and the comparison of the roles of the manufacturer as to that of the FDA with respect to drug testing and safety. Plaintiff contends that the regulations that govern medical devices are identical to or very similar to those that govern pharmaceutical drugs, so that Dr. Parisian's experience at the FDA related to medical devices is pertinent.

C. The admissibility of Dr. Parisian's testimony

The Court finds that Dr. Parisian's testimony is admissible insofar as she seeks to testify concerning the matters which plaintiff has identified as the subject of her testimony, i.e., regulations governing the approval, labeling, advertising and marketing of pharmaceutical and medical products; the processes by which the FDA determines the efficacy and safety of new drugs and new drug applications; the issues the FDA considers in the development of product labeling and marketing information; and a manufacturer's responsibility within this system. It is clear, however, from Dr. Parisian's report, deposition testimony, and testimony at the oral hearing and plaintiff's summary judgment brief that Dr. Parisian seeks to offer testimony and opinions on matters that go well beyond FDA procedures and regulations and her areas of expertise. Specifically, Dr. Parisian seeks to offer opinions as to the advisability of periodic CK testing for statin, and particularly Crestor, patients; whether CK testing could have prevented plaintiff's

kidney failure; and whether an individual who suffers from chronic pain or fibromyalgia is capable of distinguishing the pain associated with such condition from statin-induced pain. Specifically, Dr. Parisian seeks to offer the opinions that defendants failed to provide physicians with adequate warnings and directions for the use of Crestor by "the special population of patients with chronic muscle pain" since those patients may not be able to report unexplained muscle pain, tenderness or weakness, and defendants should have advised physicians regarding the risks of delay for detection of rhabdomyolysis and renal failure in patients with chronic muscle pain. Dr. Parisian is not qualified to offer such opinions because although she is a medical doctor, plaintiff has not demonstrated that there is anything in Dr. Parisian's background or training that qualifies her to testify as an expert on chronic pain patients, rhabdomyolysis, or renal failure.

Moreover, Dr. Parisian failed to demonstrate that she used scientifically valid methodology or reasoning in reaching her conclusions on these matters. At the hearing, Dr. Parisian testified that it is safe to assume that plaintiff's statin levels were increasing for some time before she went to the hospital, and CK testing could have prevented renal failure in plaintiff's case. Dr. Parisian also testified that defendants were negligent for failing to advise of the need for periodic CK testing after a physician prescribes a statin or changes the dose. However, Dr. Parisian has not performed any testing to support her theory that CK levels increase gradually over a period of time prior to the onset of rhabdomyolysis, and there is no medical evidence in the record or expert testimony that supports her assumption. In fact, Dr. Parisian conceded at the hearing that there is no evidence that individuals who have experienced rhabdomyolysis while taking Crestor had elevated CK levels prior to the onset of the condition. Hearing transcript, pp. 60-61. Nor is there any evidence in the record to show that periodic CK

testing for patients on a statin, and specifically Crestor, is recommended by any medical organization, publication, or expert on the use of statins or rhabdomyolysis.[3] In addition, Dr. Parisian points to no medical evidence in the form of test results, studies or data to support a finding that periodic CK testing could have somehow prevented plaintiff from developing kidney failure. Finally, Dr. Parisian relies solely on plaintiff's description of her own experience to conclude that an individual with fibromyalgia or chronic pain cannot distinguish such pain from statin-induced pain. Again, Dr. Parisian performed no testing or research to support her theory and there is no medical evidence in the record to support her theory.

In short, Dr. Parisian does not rely on theories regarding chronic pain, the onset of rhabdomyolysis, and the efficacy of periodic CK testing that have been tested or that have been subjected to peer review and publication, and she does not seek to testify to matters that grow naturally and directly out of research she has conducted independent of this litigation. To the contrary, Dr. Parisian's opinions regarding periodic CK testing, the onset of rhabdomyolysis, and a patient's ability to discern statin-induced pain were developed solely for purposes of testifying at the trial of plaintiff's claims and are derived, in part, from plaintiff's particular experience. As such, Dr. Parisian's testimony is not reliable and will not assist the trier of fact in understanding and disposing of the issues relevant to this case. Accordingly, Dr. Parisian's testimony on these medical matters is not admissible.

[3]There are recommendations in the literature for baseline CK testing for patients starting statin therapy. That particular recommendation is discussed below.

IV. Motion for Summary Judgment

A. Summary judgment standard

Fed. R. Civ. P. 56 allows summary judgment to secure a just and efficient determination of an action. This Court may only grant summary judgment as a matter of law when the moving party has identified, as its basis for the motion, an absence of any genuine issue of material fact. ***Celotex Corp. v. Catrett***, 477 U.S. 317, 327 (1986).

The party opposing a properly supported motion for summary judgment "may not rest upon the mere allegations or denials of his pleading, but . . . must set forth specific facts showing that there is a genuine issue for trial." ***Anderson v. Liberty Lobby***, 477 U.S. 242, 248 (1986) (quoting ***First Nat'l Bank of Arizona v. Cities Serv. Co.***, 391 U.S. 253 (1968)). The evidence of the nonmovant is to be believed and all justifiable inferences are to be drawn in his favor. ***Anderson***, 477 U.S. at 255 (citing ***Adickes v. S.H. Kress & Co.***, 398 U.S. 144, 158 (1970)).

The court is not to weigh the evidence and determine the truth of the matter but is to decide whether there is a genuine issue for trial. ***Anderson***, 477 U.S. at 249. There is no genuine issue for trial unless there is sufficient evidence favoring the nonmoving party for a jury to return a verdict for that party. ***Id.*** at 249 (citing ***Cities Serv.***, 391 U.S. at 288-289). If the evidence is merely colorable, ***Dombrowski v. Eastland,*** 387 U.S. 82, 84 (1967), or is not significantly probative, ***Cities Serv.***, 391 U.S. at 290, judgment may be granted. ***Anderson***, 477 U.S. at 249.

B. The parties' positions

Defendants move for summary judgment on plaintiff's claims on the ground that AstraZeneca Pharmaceuticals LP adequately warned plaintiff's prescribing physician of the very

side effects plaintiff allegedly suffered, and plaintiff's physician was admittedly aware of those side effects, so that the learned intermediary doctrine as codified at Ohio Rev. Code § 2307.76(C) requires dismissal of this case. Plaintiff contends that the warnings on the Crestor label were inadequate because while the label warns of possible rhabdomyolysis and renal failure, it also contains the statement that "patients should be advised to promptly report unexplained muscle pain, tenderness, or weakness." Plaintiff alleges that a patient such as herself, who suffers from chronic pain as a result of fibromyalgia, would not be able to distinguish between chronic pain and pain induced by a statin drug such as Crestor. Plaintiff alleges that because defendants knew prior to her injury that chronic pain patients make up a significant portion of the population, those patients should have been classified as a special population in the Crestor label so as to alert prescribing physicians that patients with chronic pain may not be able to identify "unexplained muscle pain, tenderness, or weakness." Plaintiff relies on the expert testimony of Dr. Parisian that she proffers to the effect that defendants failed to act as a responsible pharmaceutical company by failing to warn physicians of the safety issues chronic pain patients are exposed to when they are prescribed Crestor and defendants failed to adequately inform physicians that they should obtain baseline CK measurements as recommended by medical literature that was available while Crestor was still under development.

Plaintiff also claims that the learned intermediary doctrine does not shield defendants from liability because defendants failed to provide otherwise adequate warnings to plaintiff's physician. Specifically, she claims defendants failed to warn physicians that chronic pain patients may not be able to recognize the symptoms of the onset of rhabdomylosis, such as muscle aches, pains, and weakness, since they already suffer these symptoms, and the standard of care should

have included CK testing, which would purportedly identify the presence of rhabdomyolysis. Plaintiff concedes that her physician, Dr. Webb, was aware of the propensity of Crestor to cause rhabdomyolysis and renal failure but that he was not aware of the specific risk to chronic pain patients of the inability to recognize the new onset of statin-induced pain. Plaintiff argues that Dr. Webb's testimony that he may have still prescribed Crestor to plaintiff in light of the known risks is not dispositive of the learned intermediary issue. In support of her argument, she relies on an unpublished Arkansas district court order in which the court found similar testimony by a physician to paint with too broad a stroke since there were key issues as to whether the physician would have prescribed the drug for the same length of time and in the same amount and the testimony presented a credibility issue. She also relies on Dr. Webb's testimony that he may have followed a different pathway to get plaintiff to the set goal, perhaps starting with a 10 mg dose and upping it to 20 mg and then to 40 mg, given the following warning: "The 40 mg dose of Crestor is reserved only for those patients who have not achieved their LDL goal utilizing the 20 mg dose of Crestor once daily."[4] Webb depo., pp. 100-101. Plaintiff further notes that Dr. Webb testified that if defendants had included chronic pain patients as a special population, and if they had recommended CK baseline testing for those patients, Dr. Webb would have followed those recommendations, so that defendants have failed to establish that a lack of warnings was not the proximate cause of plaintiff's injury. ***See*** Webb depo., pp. 94, 108-09.

Plaintiff further alleges that she has produced sufficient evidence to maintain an action for

---

[4]Dr. Webb's testimony assumes this information was not on the Crestor label when he prescribed Crestor to plaintiff, when in fact it was. Webb depo., p. 102; exh. 19, p. 18. His testimony also suggests plaintiff's Crestor dosage was upped directly from 10 mg to 40 mg, but Dr. Webb indicated that he could not document from the record that this actually occurred. Webb depo., pp. 101-102.

negligence. Plaintiff relies on an August 2001 "Clinical Advisory on the Use and Safety of Statins," Pasternak, et al, "Journal of the American College of Cardiology," Vol. 40, No. 3, pp. 567-572. The Clinical Advisory acknowledges that while "[r]outine laboratory monitoring of CK is of little value in the absence of clinical signs or symptoms . . . [m]any experts also favor, and the ATP III report recommends, baseline CK measurement, reasoning that asymptomatic CK elevations are common and pre-treatment knowledge of this condition can aid in later clinical decision making." Doc. 48, exh. 16, pp. 569-70. Plaintiff notes that the Advisory further suggests that if a patient presents to their physician with muscle symptoms, the physician should "[o]btain a CK measurement if the patient reports suggestive muscle symptoms, and compare to CK blood level prior to beginning therapy," and "[i]f the patient experiences muscle [symptoms] and CK levels with either no CK elevation or a moderate elevation . . . follow the patient's symptoms and CK levels weekly until there is no longer medical concern or symptoms worsen . . ." ***Id***. at 570. Plaintiff contends that defendant knew this article was in existence but failed to heed the warnings and follow the procedures suggested. She claims that if these warnings had been placed on the Crestor label, Dr. Webb would have been alerted to the fact that plaintiff was incapable of distinguishing between her chronic pain and statin-induced pain.

In reply, defendants contend that the learned intermediary doctrine requires only that drug manufacturers warn of the known risks of prescription drugs, not the tests that should be performed to diagnose those risks. ***See In re: Meridia Prods. Liab. Litig.,*** 328 F. Supp.2d 791, 813-14 (N.D. Ohio 2004), ***aff'd,*** 447 F.3d 861 (6th Cir. 2006). Defendants argue that even if the label was inadequate because it did not advise physicians to monitor CK levels in their chronic pain patients, plaintiff's claim would nonetheless fail because she cannot establish proximate

cause between this omission and her injury. Defendants contend that Dr. Webb testified that he would have prescribed Crestor to plaintiff even if the label had contained the recommendation about CK monitoring for chronic pain patients. Defendants also allege that FDA regulations precluded them from including the warning plaintiff suggests because plaintiff has not produced any evidence that baseline or periodic CK testing would have prevented her from developing rhabdomyolysis with acute renal failure. Defendants assert that Dr. Parisian herself noted in her report that the FDA had concluded prior to approving Crestor and its labeling that because "[n]one of the patients who developed rhabdomyolysis on [Crestor] had CK elevations noted prior to the acute episiode . . . periodic CK monitoring is unlikely to be of benefit in identifying the patients at risk for rhabdomyolysis." Doc. 49, exh. 1, Parisian expert report, ¶ 116.

C. Defendants are entitled to summary judgment on the failure to warn claim

A federal court sitting in diversity must follow the law as declared by the legislature or the Supreme Court of the state whose law is applicable. ***See Erie R.R. Co. v. Tomkins***, 304 U.S. 64 (1938). The parties agree that Ohio law applies to this case.

The concept of strict liability in tort for a defective product is codified at Ohio Rev. Code Ch. 2703. Section 2703.03 provides that a manufacturer is subject to liability for compensatory damages based on a product liability claim only if the plaintiff proves, by a preponderance of the evidence, that (1) "the manufacturer's product in question was defective in manufacture or construction as described in section 2307.74 of the Revised Code, was defective in design or formulation as described in section 2307.75 of the Revised Code, was defective due to inadequate warning or instruction as described in section 2307.76 of the Revised Code, or was defective because it did not conform to a representation made by its manufacturer as described in section

2307.77 of the Revised Code"; and (2) the defect was a proximate cause of harm for which the plaintiff seeks to recover compensatory damages.

Ohio Rev. Code § 2307.76 provides, in pertinent part, that:

> (A) Subject to divisions (B) and (C) of this section, a product is defective due to inadequate warning or instruction if either of the following applies:
>
> (1) It is defective due to inadequate warning or instruction at the time of marketing if, when it left the control of its manufacturer, both of the following applied:
>
> (a) The manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product and that allegedly caused harm for which the claimant seeks to recover compensatory damages;
>
> (b) The manufacturer failed to provide the warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which the claimant seeks to recover compensatory damages and in light of the likely seriousness of that harm.
>
> (2) It is defective due to inadequate post-marketing warning or instruction if, at a relevant time after it left the control of its manufacturer, both of the following applied:
>
> (a) The manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product and that allegedly caused harm for which the claimant seeks to recover compensatory damages;
>
> (b) The manufacturer failed to provide the post-marketing warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which the claimant seeks to recover compensatory damages and in light of the likely seriousness of that harm.
>
> (B) A product is not defective due to lack of warning or instruction or inadequate warning or instruction as a result of the failure of its manufacturer to warn or instruct about an open and obvious risk or a risk that is a matter of common knowledge.

> (C) An ethical drug is not defective due to inadequate warning or instruction if its manufacturer provides otherwise adequate warning and instruction to the physician or other legally authorized person who prescribes or dispenses that ethical drug for a claimant in question and if the federal food and drug administration has not provided that warning or instruction relative to that ethical drug is to be given directly to the ultimate user of it.

The question of the adequacy of the warning given in strict liability cases is of central importance in determining whether the product is unreasonably dangerous. ***Graham v. American Cyanamid Co.,*** 2000 WL 1911431 *9 (S.D. Ohio 2000) (citing ***Seley v. G.D. Searle & Co.,*** 67 Ohio St.2d 192, 197 (1981)). If an adequate warning has been provided for a pharmaceutical product, then the manufacturer cannot be held strictly liable, irrespective of whether there is a causal connection between the plaintiff's use of the drug and the plaintiff's injury, and despite the fact that the product is unavoidably unsafe. ***Id.*** (citing ***Seley,*** 67 Ohio St.2d at 197). A warning is adequate if it reasonably discloses to the medical profession all risks inherent in the use of the drug which the manufacturer knew or should have known to exist. ***See Seley***, 67 Ohio St.2d at 198. "A warning may be unreasonable in its factual content, its expression of the facts, or the method or form in which it is conveyed." ***Graham,*** 2000 WL 1911431 (citing ***Seley,*** 67 Ohio St.2d at 198). "The adequacy of warnings is measured not only by what is stated, but also by the manner in which it is stated." ***Id.*** "A reasonable warning not only conveys a fair indication of the nature of the dangers involved, but also warns with the degree of intensity demanded by the nature of the risk." ***Id.***

Plaintiff has not produced sufficient evidence to create a genuine issue of material fact as to whether defendants can be held liable for failing to warn of the risks associated with Crestor under a strict liability theory. The evidence establishes that defendants knew of a risk of

rhabdomyolysis associated with the use of Crestor; they warned of this risk on the Crestor label in no uncertain terms; and plaintiff suffered the very injury warned of as a proximate result of her use of Crestor. Plaintiff has not shown that the possibility that an individual who suffers from chronic pain will not necessarily be able to distinguish pain and muscle aches and weakness caused by rhadomyolysis from their preexisting symptoms is an additional, independent risk posed by Crestor. Plaintiff has not produced evidence to show that Crestor decreases the ability of an individual who suffers from chronic pain to detect the symptoms of the onset of rhabdomyolysis. Rather, any increased risk that such an individual will be unable to detect the onset of rhabdomyolysis caused by Crestor is created by that particular individual's preexisting condition.

Moreover, there is no evidence that testing has been performed to validate plaintiff's theory that a patient who suffers from chronic pain is unable to distinguish the muscle pain caused by rhabdomyolysis from their chronic pain. Instead, plaintiff relies on (1) her anecdotal testimony; (2) the testimony of Dr. Webb that if an individual complained after being put on a statin that they were experiencing the same pain that they always had, he "probably [would] not" be able to distinguish between statin-induced muscle injury and preexisting chronic pain, Webb depo., p. 105; and (3) the testimony of Dr. Blatman, who testified that based on his experience, he does not think that an individual with fibromyalgia who suffers from pain all over their body and who develops myalgia pain insidiously as a result of taking a statin would be able to distinguish the two types of pain. Blatman depo., pp. 47-49. This testimony, if accepted is true, is insufficient to permit a reasonable jury to find that chronic pain and the pain associated with the onset of rhabdomyolysis are indistinguishable for the reasons explained below.

First, plaintiff's testimony regarding her own experience, standing alone, is insufficient to establish that chronic pain patients are typically unable to distinguish between their chronic pain and statin-induced pain. In fact, plaintiff's testimony does not demonstrate that she was unable to distinguish between the two types of pain. Plaintiff indicated in the portions of her deposition testimony submitted by the parties that she did notice a change in her symptoms in the weeks after she started on 40 mg Crestor in May of 2004 and before she went to the hospital in July of 2004. Plaintiff testified that in May and June of 2004, her pain got worse; her kidney flow was abnormal in that there was not much of a flow and her urine was dark; and she was getting weaker and weaker. Doc. 43, Exh. E, pp. 121-122. Plaintiff testified that she did not talk to her doctors because she thought these symptoms were part of her fibromyalgia. Id. The fact that plaintiff mistakenly attributed her new or more severe symptoms to fibromyalgia does not, however, support a finding that the symptoms were actually indistinguishable from her chronic pain and weakness. Second, Dr. Webb's testimony as to his presumed inability to distinguish between identical complaints of pain by a patient is not helpful because his testimony assumes that statin-induced pain and chronic pain such as fibromyalgia patients experience are in fact similar. Finally, Dr. Blatman's testimony demonstrates only that it is his belief based on his experience as a physician that a fibromyalgia patient who does not develop new or exacerbated symptoms shortly after starting on a medication may have a difficult time distinguishing between their chronic pain and pain attributable to the medication. Because Dr. Blatman holds this belief based only on his experience as a physician, however, his testimony indicates nothing more than that the alleged risk of being unable to distinguish between statin-induced pain and chronic pain must be deemed to be "an open and obvious risk or a risk that is a matter of common knowledge"

among physicians, rather than a scientifically established risk, in which case defendants had no duty to warn about the risk. ***See*** Ohio Rev. Code § 2307.76. Thus, a reasonable jury could not find based on the evidence presented that defendants violated a duty they owed to plaintiff by failing to advise on the Crestor label that individuals who suffer from chronic pain may not be able to distinguish such pain from pain associated with rhabdomyolysis.

Nor could a reasonable jury find that defendants violated a duty to warn by failing to advise that CK testing should be performed as part of the standard of care for patients prescribed Crestor. There is not a scintilla of competent evidence in the record to support a finding that baseline and periodic CK testing would be of any benefit to patients taking Crestor, including patients with chronic pain. There is likewise no competent evidence to support plaintiff's position that baseline and periodic CK testing would have alerted her physician to the presence of rhadomyolysis in a sufficiently timely manner to prevent her renal failure.

For these reasons, a reasonable jury could not find based on the evidence presented that defendants violated a duty to warn of the risk that caused plaintiff's injury. Defendants are entitled to summary judgment on plaintiff's claim that defendants are strictly liable for a failure to warn as a matter of law.

D. Negligence claim

A claimant may also assert a claim for negligent failure to warn under Ohio law. ***Graham,*** 2000 WL 1911431 *10, n.10 (citing ***Crislip v. TCH Liquidating Co.***, 52 Ohio St.3d 251, 256 (1990)). A claim for negligent failure to warn has three basic elements: (1) a duty to warn against reasonably foreseeable risks; (2) breach of such a duty; and (3) injury that is proximately caused by the breach. ***Id***. (citing ***Briney v. Sears, Roebuck & Co.***, 782 F.2d 585, 587 (6th Cir. 1986)

(citing ***Menifee v. Ohio Welding Products, Inc***., 15 Ohio St.3d 75, 77, 472 N.E.2d 707 (1984)). The manufacturer must give suitable warning of a dangerous propensity that may result from use of the product. ***Id.*** at *11 (citing ***Temple v. Wean United, Inc.***, 50 Ohio St.2d 317, 364 N.E.2d 27 (1977)). The warning necessary to satisfy the duty of ordinary care will vary depending on the facts of each case. ***Id.*** (citing ***Miles v. Kohli & Kaliher Assoc., Ltd.***, 917 F.2d 235, 243 (6th Cir. 1990)).

Plaintiff alleges that defendants were negligent in failing to place a recommendation on the Crestor label that baseline CK testing be performed on patients prior to undergoing statin therapy in order to give physicians an additional tool in diagnosing statin-induced injury. Plaintiff claims that the only method recommended by defendants for identifying the onset of rhabdomyolysis - reporting unexplained pain and weakness to one's doctor - is not infallible. Plaintiff argues that because a chronic pain patient is not able to recognize the clinical markers of rhabdomyolysis, the standard of care should include CK testing, which would identify the presence of the condition. Plaintiff points to the Adult Treatment Plan III Guidelines[5] recommendation that baseline testing be performed and that a CK measurement be obtained for comparison purposes if a patient presents to their physician with muscle symptoms in support of her theory that baseline and periodic CK testing is critical for chronic pain patients since they constantly exhibit muscle aches, pains and weakness. Plaintiff claims that defendants' failure to recommend "[t]hese simple steps" directly and proximately caused plaintiff's injury.

[5]Dr. Parisian identified these guidelines at the oral hearing as guidelines that are formulated for management of patients' lipid and cholesterol levels.

As stated above, there is no admissible evidence in the record to support a finding that baseline CK testing alone or in combination with periodic CK testing aids in the early detection of rhabdomyolysis for any population of patients or that such testing would have detected plaintiff's rhadomyolysis in time to prevent her injury. Moreover, the ATP III Guidelines recommendation for baseline testing coupled with follow-up testing if a patient reports to her physician with muscle symptoms would be of little value in preventing injury to a chronic pain patient if one accepts plaintiff's position that a chronic pain patient is unable to recognize statin-induced muscle symptoms. Such a patient, believing her muscle symptoms to be part of her chronic condition, would not know to report her symptoms to a physician so as to potentially alert the physician to the need to perform CK testing. For these reasons, a reasonable jury could not find that defendants had a duty to advise of the need for baseline and periodic CK testing or that their failure to advise physicians that baseline and follow-up testing should be performed on Crestor patients who report muscle symptoms was the proximate cause of plaintiff's kidney failure. Because there is insufficient evidence to create a genuine issue of material fact as to either the existence of a duty or proximate cause between an alleged breach of a duty and plaintiff's injury, defendants are entitled to summary judgment on plaintiff's negligence claim.

V. Conclusion

In accordance with the foregoing, defendants' motion to exclude the testimony of Dr. Suzanne Parisian (doc. 42) is **GRANTED in part** as set forth herein (doc. 43) and defendants' motion for summary judgment (doc. 39) is **GRANTED**. This case is **DISMISSED** and is **TERMINATED** on the docket of the Court at plaintiff's cost.

IT IS SO ORDERED.

S/ Herman J. Weber
HERMAN J. WEBER, SENIOR JUDGE
UNITED STATES DISTRICT COURT